DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 20, 2015

Cardinal Health
% Ms. Allison Scott
Navigant Consulting Incorporated
9001 Wesleyan Road, Suite 200
Indianapolis, Indiana 46268

Re: K143016
Trade/Device Name: Cardinal Health NPWT PRO/PRO to GO/PRO at Home Systems
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: March 16, 2015
Received: March 17, 2015

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143016

Device Name

Cardinal Health NPWT PRO/PRO to GO/PRO at Home Systems

Indications for Use *(Describe)*

The Cardinal Health NPWT PRO/PRO to GO/PRO at Home systems are an integrated wound management system, indicated for the application of continual or intermittent negative pressure wound therapy to the wound as the device may promote wound healing by the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials. The systems are intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The systems are intended for use in acute, extended and home care settings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. Submitter Information

Cardinal Health
1500 S Waukegan Road
Waukegan, IL 60085

Contact Person: Allison Scott, RAC
317.228.8700
Allison.Scott@Navigant.com

Date Prepared: April 14, 2015

II. Device Information

Name of Device: Cardinal Health NPWT Pro
Cardinal Health NPWT Pro to Go
Cardinal Health NPWT Pro at Home
Common Name: Negative Pressure Wound Therapy Powered Suction Pump
Classification Name(s): Powered Suction Pump (21 CFR 878.4780)
Regulatory Class: II
Product Code: OMP

III. Predicate Device

510(k) Number	Device Name	Submitter Name
K111333	Antlia III WTS	Innovative Therapies, Inc.

This predicate has not been subject to a design-related recall.

The SVED® Wound Treatment System (K093564) submitted by Innovative Therapies, Inc. is used as a reference device in this submission.

IV. Device Description

The Cardinal Health NPWT PRO family of systems are AC-powered, portable suction devices with battery backup that provide localized negative pressure wound therapy when used with the Cardinal NPWT Dressings to remove fluid, irrigation solutions and infectious materials from the wound. The systems consist of a powered suction pump device with a built-in placement holder for the fluid collection canister, various sizes and shapes of polyurethane foam dressings, canister tubing with clamps and connectors, and polyurethane drapes with adhesive. The systems are intended for use on patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns,

ulcers (such as diabetic or pressure), flaps and grafts. The Cardinal Health NPWT PRO family of systems provides care in the acute, extended and home care settings.

The Cardinal Health NPWT PRO family of systems consists of the same powered suction pump components and foam dressing components, and functions the same as the Antlia III Wound Treatment System. The Cardinal Health NPWT PRO family of systems includes a built-in placement holder for the 300cc or 500cc collection canisters. They have a pushbutton ON/OFF operation with five user-selectable pressure settings. The system produces optional negative pressure settings of 50mmHg, 75mmHg, l00mmHg, l25mmHg, and l50mmHg. It has alarms for Low Pressure/Leak, Full Canister, Low Battery and Service Timer. These alarms include both audible and visual indications.

The purpose of this 510(k) submission is to update the Antlia III Wound Treatment System (WTS) into three separate, but similar devices: Cardinal Health NPWT PRO, Cardinal Health NPWT PRO to Go, and Cardinal Health NPWT PRO at Home. The following updates have been made:

- The Cardinal Health NPWT PRO family of systems has an updated indications for use to include partial-thickness burns. This better aligns the indications for use with the "OMP" regulation definition.
- The Cardinal Health NPWT PRO family of systems provides care in the acute and extended clinical and home care settings
- There is an enhancement to the pressure control for full canister alarm
- There are enhancements to the therapy timer
- There are updates to the pump graphics and associated software controls

V. Intended Use(s)

The Cardinal Health NPWT PRO/PRO to GO/PRO at Home systems are an integrated wound management system, indicated for the application of continual or intermittent negative pressure wound therapy to the wound as the device may promote wound healing by the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials. The systems are intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The systems are intended for use in acute, extended and home care settings.

VI. Comparison of Technological Characteristics

This submission is to provide an update to the existing cleared Antlia III WTS into three different configurations. The subject and predicate devices are based on the following same technical elements:

- Continuous and Intermittent negative pressure wound therapy treatment modes
- 50mmHg, 75mmHg, 100mmHg, 125mmHg & 150mmHg Negative Pressure Ranges
- Pressure sensing technology within the pump
- Available for use with 300cc and 500cc canisters
- Use AC and Rechargeable battery

The following differences exist between the subject and predicate devices:

- The Cardinal Health NPWT PRO family of systems has updated Indications for Use to include partial-thickness burns. This better aligns the Indications for Use with the "OMP" regulation definition.
- The Cardinal Health NPWT PRO family of systems provides care in the acute and extended clinical and home care settings
- The Cardinal Health NPWT PRO systems have had other changes including:
    - Enhanced pressure control for full canister alarm
    - Enhanced therapy timer
    - Updates to the pump graphics and associated software controls

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Antlia III WTS. The system complies with the IEC 60601-1 and IEC 60601-1-11 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern, since a failure or latent flaw in the software could directly result in minor injury to the patient or operator.

Clinical Usability Testing

A single-center, unblinded, observational, simulated use usability evaluation of the Cardinal Health NPWT PRO at Home System with 34 adult Healthcare Professionals (HCPs) and lay-user Subjects as patient/caregiver surrogates. Following enrollment and training, approximately half of each Subject cohort was guided through either [1] a Directed Use Case trial in which they were asked to read and follow the written instructions to complete study tasks (documentation validation), or through [2] an Unassisted Use Case trial in which the written instructions were made available but the

Subjects were free to decide to use them (interface usability validation). A final interview to capture root cause for any use errors or close calls, and any remaining Subject feedback or questions was conducted before releasing the Subject from the study. Results from the study were used to update the risk analysis plan and user manual, as needed.

VIII. Conclusions

The clinical usability testing and software verification and validation demonstrate that the Cardinal Health NPWT PRO family of systems should perform as well as the predicate device in the specified use conditions.